REMARKS

Claims 9 and 19-21 are pending in this application. Claim 9 is amended to correct informalities as suggested by the examiner. Therefore, no new matter is introduced. The Office Action is discussed below:

Objection to the Specification:

On page 2 of the Office Action, the examiner has objected to the specification for informalities and asserts that the title of the invention is not descriptive. Applicants amend the title as suggested by the examiner to read as "A Method of Preparing an Organ by Perfusion".

Claim Objection:

On pages 3-4 of the Office Action, the examiner has objected to claim 9 for various informalities. Applicants amend the claim to correct informalities as suggested by the examiner.

Obviousness Rejection Maintained:

On pages 5-6 of the Office Action, the examiner has maintained the rejection of claims 9 and 19-21 under 35 U.S.C. 103(a) allegedly as being unpatentable over Smith *et al.* (U.S. 6,713,606) in view of the Baxter SOLTRAN solution product #FKB4708G and Varty *et al.* (Abstract, BMJ 1994, 308:575). On pages 6-8 of the Office Action, the examiner provided response to the arguments submitted previously. Applicants respectfully disagree with the examiner and submit the following in order to assist the examiner in distinguishing the claimed invention from the cited references:

In this context, applicants request the examiner to consider that:

"All words in a claim must be considered in judging the patentability

> of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).
>
> *See* MPEP §2143.03 at 2100-142 (Rev. 6, September 2007).

Applicants submit that the cited references alone or in combination do not disclose all claim limitations, as clarified previously and further discussed herein.

The examiner believes that a person skilled in the art would be able to combine Smith *et al.* disclosure with Baxter SOLTRAN solution product #FKB4708G and Varty *et al.* to arrive at the claimed invention. Applicants refer to the previous response that, mere fact that references can be combined or modified does not render the resultant combination obvious. In the method of the present invention it has now been found that organs perfused with the novel preparation absorb the complement inhibitor agent and that the perfused organs will retain the agent for sufficient periods such that the agent is capable of protecting an organ, such as the kidney or a tissue, from complement attack both during storage and after transplantation.

Applicant refer the examiner to Figure 1 of the application and the associated description, for example, wherein it is shown that the complement inhibitory effect is advantageously still seen for a period post-transplant: the data shows that the organs perfused according to the invention had improved renal function post-transplantation during the first week post-transplantation.

Nonetheless, there is nothing in the cited references that suggests one of ordinary skill, without hindsight, that a formulation according to the invention used in the method of the invention would provide this benefit. On page 6 of the Office Action, the examiner asserted that SOLTRAN is a "commonly used" flush solution, however, that does not offer any justification nor provide any motivation to a skilled artisan to combine the flush solution, to be used as a transport solution, to the recited polypeptide to arrive at the claimed invention.

Although, the examiner has focused on the existence and previous uses of SOLTRAN (Baxter and Varty), the cited references concern the use of SOLTRAN alone as a perfusion solution for storage. Applicants reiterate, the claimed invention is very different in that flush storage solution (*e.g.,* SOLTRAN) is being used in an *entirely different and non-obvious context,* namely as a delivery vehicle for the soluble derivative to be carried to where it is needed in the organ. Accordingly, a flush storage solution must be such that the activity of the soluble derivative will be maintained and delivered to the sites in the organ where it is needed.

It is apparent from above that Baxter and Varty provide no suggestion, motivation or expectation of successfully achieving such a result. In other words, the examiner has not been able to identify a reason provided by the prior art references or common knowledge in the field for making the combination. More specifically, there is no suggestion that the examiner could provide for use of a storage solution as a transportation solution.

Further, the combination of the Baxter and Varty references with the Smith reference is nowhere supported by the references or in the common knowledge of the art. Accordingly, the rejection calls to mind the Federal Circuit decision of *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998), where the court explained:

> As this court stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.,* 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); *see also Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements"). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint to defeat the patentability of the claimed invention. Such an approach would be an "illogical and inappropriate process by which to determine patentability." *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

> To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventors and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

Applicants submit that the rejection does not satisfy the strictures of the *Rouffet* decision. The references are not combinable without proscribed hindsight.

In response to the arguments, on pages 6-8 of the Office Action, the examiner has relied on *KSR, 127 S. Ct. at 1741* that the analysis under 35 U.S.C. 103 need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the "inferences and creative steps that a person of ordinary skill in the art would employ." *Id. at 1741 and Id. at 1742.* Applicants respectfully disagree with the examiner and point out that the cited case law is not applicable in the current context, and submit that:

> When claims are directed to biotechnology inventions like viruses and vaccines, the inquiry turns to similarities and differences between the claimed subject matter and the prior art. In basing obviousness on the availability of substitutions, *KSR v. Teleflex* presupposes that the art gives reasons to make a modification. However, where the art is unpredictable, such as in the biotechnology and chemical arts, *KSR*'s focus on "identifiable, predictable solutions" present a difficult hurdle for the examiner because an alleged potential solution based upon the prior art is not likely to be genuinely predictable. *Eisai Co. v. Dr. Reddy's Laboratories Ltd.*, 87 USPQ2d 1452, 1456-57 (Fed. Cir. 2008).

Regarding the unpredictable nature of the current invention, applicants herewith submit a declaration of Dr. Richard Anthony Godwin Smith that it was not obvious to a person skilled in the art that such a benefit would be predictable and obtainable by using a solution which has been known to be commonly used as a solution for different purpose.

As stated in Dr. Smith's declaration, one following the teachings of the field regarding transplant solutions, such as the University of Wisconsin solution, would very likely end up destroying their soluble derivative. There is simply no teaching to direct one skilled in the art away from transplant solutions to flush solutions, particularly those lacking glutathione (see sections 3-5 of the declaration).

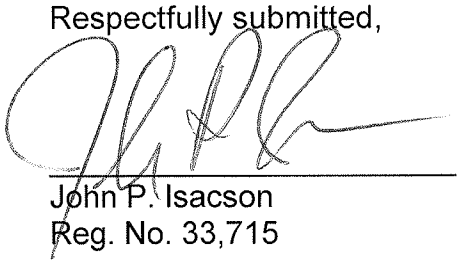
Therefore, it would have been unpredictable to one skilled in the art at the time of the invention to use the recited flush storage solution as a transplant solution in a method of preparing an organ by perfusion prior to transplantation or storage of the organ.

In view of the above discussion and clarifications, applicants point out that the examiner has not provided any factual rationale to support the purported combinations. The examiner also has not provided any reason why one skilled in the art would be motivated to employ a flush solution, as recited in claim 9, as a transplant solution without a reasonable expectation of success. Applicants, therefore, submit that a *prima facie* case of obviousness has not been established. Accordingly, withdrawal of the obviousness rejection is solicited.

REQUEST

Applicants submit that claims 9 and 19-21 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 434-1610 should there be any questions.

Respectfully submitted,



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